Roche

Pharmaceuticals

2004N-0133
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fischers Lane, Room 1061
Rockville, MD 20852
U.S.A.

Basel, May 11, 2004
Re: Request to speak at the Public Meeting on Electronic Records; Electronic Signatures (Part 11) National Transportation Safety Board Conference Center, Washington, DC, June 11, 2004 (2004N-0133)

Dear Madam, Dear Sir,

On behalf of F. Hoffmann-La Roche Ltd, we would like to request the opportunity to have our Dr. Peter Bosshard speak at the above public meeting. Attached is an abstract of the presentation we propose that he will to give.

By way of background, Roche is a leading healthcare company with a uniquely broad spectrum of innovative products. Our products and services address prevention, diagnosis and treatment of diseases, thus enhancing well-being and quality of life. The company employs around 65,000 people and sells its products in over 150 countries.
The focus of Roche is not solely the diagnosis and treatment of manifest disease. The integrated healthcare approach is increasingly offering ways of identifying and targeting diseases early, when their damaging effects can still be prevented. Arranged in two operative divisions, our global mission today and tomorrow is to create exceptional added value in healthcare. These two units are Pharmaceuticals and Diagnostics.

This presentation and abstract was forwarded for comment to a Roche internal expert group dealing with the topic of electronic records and signatures, consisting of roughly 50 members from various countries.

Thank you for considering our request.

Yours sincerely,

F. Hoffmann-La Roche Ltd

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1. *Abstract for Electronic Records and Electronic Signatures FDA Public Meeting, Washington DC, June 11th 2004*

We would like to address the topics for discussion and comment as stated in your Federal Register publication (Federal Register: April 8, 2004 (Volume 69, Number 68), Page 18591-18593)

In addition we would like to talk about the following four topics:

1.1 Use of audit trail information with the meaning of initials vs. a person's signature.
In the paper world there is a clear distinction between a set of initials and a signature. Initials serve usually to confirm a single process step. If in an electronic system the audit trail captures this information an electronic signature would not add any quality. In addition we have found instances of records that have several hundred initials. It is not realistic that an operator enters his password or user-ID and password up so many times during an operation. We would appreciate if the audit trail could be used for this purpose.

1.2 Audit trail on process equipment should be optional
It should be possible to run process equipment without the use of an audit trail. In data processing the lifecycle for new features is very short, although in classical engineering durability is still valued. Therefore today we still find old but reliable equipment that runs on old operating systems. It is not only technologically impossible to build audit trails into such equipment, but it might even introduce errors or problems into the equipment.
For modern equipment the audit trail should remain an optional feature. An audit trail should only be applicable if it is important to identify the person who was responsible for a certain action.

1.3 Option to select version control or audit trail
If versions of records are controlled, an audit trail should not be necessary.
Some graphical programs like CAD (Computer Aided Design) applications do not provide an audit trail. Audit trail information would be very difficult to detect on the drawings. Also an audit trail for text records may be difficult to read and could lead to more misunderstandings than a proper version control. Misunderstandings can then lead to quality problems.
There should be the option to decide whether to use audit trail or version control.

1.4 Allow open equipment in areas with restricted access
More and more process equipment is being used in restricted areas which contain microprocessors and touch panels as the interface to the operator. These panels are used for simple operations such as switching a machine on or off. These panels have the advantage in comparison with traditional electric switchboards that they are easier to clean and present less probability of contamination.